

EXHIBIT 2

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San Francisco County Superior Court

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7 **SUPERIOR COURT OF THE STATE OF CALIFORNIA**

8 **COUNTY OF SAN FRANCISCO**

9 WAYNE RUDEN,
10

11 Plaintiff,

12 vs.

13 C.R. BARD, INC., a New Jersey
corporation, BARD PERIPHERAL
14 VASCULAR, INC., (a subsidiary and/or
division of defendant C.R. BARD, INC.) an
15 Arizona corporation, CALIFORNIA
PACIFIC MEDICAL CENTER, and DOES
16 1-100 INCLUSIVE,

17 Defendants.

Case No. **CGC-15-548341**

COMPLAINT FOR DAMAGES

DEMAND FOR JURY TRIAL

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COMPLAINT

ORIGINAL

FAXED

1 **COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL**

2 Plaintiff WAYNE RUDEN (the "Plaintiff"), by and through his undersigned attorneys,
3 hereby sues Defendants C.R. BARD, INC.; BARD PERIPHERAL VASCULAR, INC., a
4 subsidiary corporation and/or division of C.R. BARD, INC. (collectively the "Bard Defendants");
5 California Pacific Medical Center ("CPMC"), and DOES 1 to 100 inclusive (collectively, the
6 "Defendants") and allege as follows:

- 7 1. This is an action for damages against the Bard Defendants and Does relating to the
8 development, testing, assembling, manufacture, packaging, labeling, preparing,
9 distribution, marketing, supplying, and/or selling the defective product sold under the
10 name "inferior vena cava filter" (hereinafter "IVC filter").
- 11 2. This is an action for damages against all Defendants relating to the supplying, providing,
12 implanting and/or selling the defective IVC filter and failure to reasonably disclose or to
13 reasonably inform Plaintiff Wayne Ruden of defects which were known or apparent at the
14 time of implantation or that became known or apparent at a later date, in derogation of
15 duties to provide reasonable professional care or to uphold fiduciary and confidential
16 duties to the Plaintiff.

17 **PARTIES**

18 **Plaintiff**

- 19 3. Plaintiff, Wayne Ruden, is and has at all pertinent times been a resident of San Francisco,
20 California, which is located in the City and County of San Francisco, California.
- 21 4. Venue is proper before this Court as a substantial part of the events or omissions giving
22 rise to the claim occurred within this County, Defendant CPMC has a principal place of
23 business in this County, and the Defendants regularly conduct business in this County.

24 **Defendants**

- 25 5. The true names and capacities, whether individual, corporate, associate, governmental or
26 otherwise, of Defendants DOES 1 through 100, inclusive, are unknown to Plaintiff at this
27 time, who therefore sues said Defendants by such fictitious names. When the true names
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1 and capacities of said Defendants have been ascertained, Plaintiff will amend this
2 complaint accordingly. Plaintiff is informed and believes, and thereon alleges, that
3 each Defendant designated herein as a DOE is responsible, negligently or in some other
4 actionable manner, for the events and happenings hereinafter referred to, and caused
5 injuries and damages proximately thereby to the Plaintiff, as hereinafter alleged.

6 6. At all times herein mentioned, each of the Defendants was the agent, servant, partner,
7 licensee and licensor, aider and abettor, co-conspirator, employee and/or joint venture of
8 its co-Defendants, and each of them, and at all said times each Defendant was
9 acting in the full course and scope of said agency, service, employment, partnership,
10 conspiracy, license, and/or joint venture and rendered substantial assistance and
11 encouragement to the other Defendants, knowing that its conduct constituted breach of
12 duty owed to Plaintiffs. Plaintiffs are informed and believe, and thereon allege that at
13 all times herein mentioned, Defendants **C.R. BARD, INC., DEFENDANT BARD**
14 **PERIPHERAL VASCULAR, INC., DEFENDANT CALIFORNIA PACIFIC**
15 **MEDICAL CENTER and DOES 1-100 INCLUSIVE** were individuals, corporations,
16 partnerships and/or unincorporated associations organized and existing under and by
17 virtue of the laws of the State of California, or the laws of some other state or foreign
18 jurisdiction, and that said Defendants, and each of them, were and are authorized to do
19 and are doing business in the State of California.

20 7. Defendant C.R. Bard, Inc. ("Bard") is a corporation duly organized and existing under
21 the laws of the state of Delaware and has its principal place of business in New Jersey.
22 Bard, at all times relevant to this action, designed, set specifications, manufactured,
23 prepared, compounded, assembled, processed, marketed, distributed, and sold the Bard
24 Recovery Filter ("BRF") to be implanted in patients throughout the United States,
25 including California. At all times relevant hereto, Defendant Bard was or has been
26 engaged in business in California, and has conducted substantial business activity in
27 California. Defendant has also carried on solicitations or service activities in the State of
28 California.

1 8. Defendant Bard Peripheral Vascular, Inc. ("BPV") is a wholly owned subsidiary
2 corporation of defendant Bard, with its principal place of business at 1625 West 3rd
3 Street, Tempe, Arizona. BPV at all times relevant to this action, designed, set
4 specifications, manufactured, prepared, compounded, assembled, processed, marketed,
5 distributed, and sold the BRF to be implanted in patients throughout the United States,
6 including California. At all times relevant hereto, Defendant BPV was or has been
7 engaged in business in California, and has conducted substantial business activity in
8 California. Defendant has also carried on solicitations or service activities in the State of
9 California.

10 9. Defendant CPMC is a general medical and surgical hospital and academic medical
11 center operating at multiple locations in San Francisco, California, where its principal
12 place of business is located. CPMC, at all times relevant to this action, distributed, sold
13 and utilized the BRF and implanted the same through its agents, including in the body of
14 Plaintiff. At all times relevant hereto, Defendant CPMC was or has been engaged in
15 business in California, and has conducted substantial business activity in California.
16 Defendant has also carried on solicitations or service activities in the State of California.

17 **JURISDICTION AND VENUE**

18 10. Jurisdiction is proper in this court because each defendant has engaged in and conducted
19 substantial business activity in California, and because all of the events and omissions
20 giving rise to liability in this matter occurred in California. The Bard defendants
21 manufactured and sold the BRF, which entered California through the stream of
22 commerce. CPMC is located in California.

23 11. Venue is proper in this court because Defendant CPMC resides in the City and County of
24 San Francisco County, because the decision to insert the BRF in plaintiff's body was
25 made in the City and County of San Francisco, and because various of the breaches, bad
26 acts and omissions alleged herein occurred in the City and County of San Francisco.

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A. GENERAL FACTUAL ALLEGATIONS (ALL DEFENDANTS AND DOES 1-100 INCLUSIVE)

12. Plaintiff brings this case for serious injuries he suffered as a result of a surgically implanted medical device, known as a Bard Recovery Filter ("BRF"), which fractured, resulting in the embolization of two arm fragments into the proximal right pulmonary arteries, and the embolization of one fractured arm fragment into the right atrium of his heart, where it remains to this day.

13. The BRF was designed, manufactured, prepared, compounded, assembled, processed, labeled, marketed, distributed, and sold by Defendants for prevention of blood clots (thrombi) from traveling from the lower portions of the body to the heart and lungs.

14. Prior to Plaintiff Wayne Ruden being implanted with a BRF on or about March 2004, Defendants knew or should have known that the device was defective and unreasonably dangerous for, *inter alia*, the following reasons:

15. a. Defendants failed to conduct any clinical testing, such as animal studies, to determine how the device would function once permanently implanted in the human body.

b. Defendants knew and/or should have known that the BRF had a high rate of fracture, migration, and excessive tilting and perforation of the vena cava wall once implanted in the human body. Defendants know and/or should have known that such failures exposed patients to serious injuries, including: death; hemorrhage; cardiac/pericardial tamponade; cardiac arrhythmia and other symptoms similar to myocardial infarction; severe and persistent pain; perforations of tissue, vessels, and organs; and inability to remove the device. Further, Defendants knew and should have known that these risks for the BRF were and are substantially higher than other similar devices.

c. Further, Defendants knew and/or should have known that the BRF contained conditions which Defendants did not intend, which resulted in the device not performing as safely as the ordinary customer would expect.

d. Despite being aware of these risks, Defendants misrepresented, omitted, and/or failed to provide adequate warnings of these risks or instructions for safe use.

e. Even when Defendants designed and began marketing what they alleged to be a device that specifically reduced these risks, they still failed to issue a recall or notify consumers that a safer device was available.

INFERIOR VENA CAVA FILTERS GENERALLY

16. The IVC filter at issue in this case was manufactured, marketed, and sold by the Bard Defendants, C.R. Bard, Inc. and/or Bard Peripheral Vascular, Inc., at all pertinent times. The Bard Defendants continue to manufacture and sell the BRF's successor, the G2 device, throughout the United States of America and abroad.

17. IVC Filters first came on the medical market decades ago. Over the years, several different medical device manufacturers have introduced several different designs of IVC filters.

18. An IVC filter is a device that is designed to filter or "catch" blood clots (called "thrombi") that travel from the lower portions of the body to the heart and lungs. IVC filters may be designed to be implanted, either permanently or temporarily, in the human body, more specifically, within the inferior vena cava.

19. The inferior vena cava is a vein that returns blood to the heart from the lower portions of the body. In certain people, for various reasons, thrombi travel from the vessels in the legs and pelvis, through the vena cava and into the lungs. Oftentimes, these thrombi develop in the deep leg veins. These thrombi are called "deep vein thrombosis" or "DVT." Once thrombi reach the lungs, they are considered "pulmonary emboli" or "PE." Pulmonary emboli present grave risks to human health.

20. Certain people are at increased risk for the development of DVT or PE. Those people at risk for DVT/PE can undergo medical treatment to manage the risk. For example, a doctor may prescribe medications like Heparin, Warfarin, or Lovenox to regulate the clotting factor of the blood. In some people who are at high risk for DVT/PE, or who cannot manage their conditions with medications, physicians may recommend surgically implanting an IVC filter to prevent thromboembolic events.

21. Over the years, a concern developed within the medical community (and was shared by

1 IVC filter manufacturers) that an IVC filter should be designed and manufactured so that
 2 it can be retrieved from the human body. Eventually, retrievable IVC filter designs were
 3 offered in the market. However, these IVC filter designs were not intended to remain
 4 within the human body for indeterminate periods of time. In other words, the initial
 5 designs of retrievable IVC filters were intended to remain implanted for a finite period of
 6 time. The BRF (discussed in more detail *infra*) was introduced to the market in late 2002
 7 or 2003 (and subsequently removed from the market in late 2005) as an IVC filter that
 8 was able to be retrieved after an indeterminate time of placement within the human body.

9 **THE BARD RECOVERY FILTER**

- 10 22. The BRF is a medical device constructed of a nickel-titanium alloy (also called
 11 “Nitinol”) designed to filter blood clots (thrombi) from the human circulatory system.
 12 Nitinol material is unique. Nitinol is actually an acronym that stands for Nickel
 13 Titanium Naval Ordnance Laboratory. Nitinol is also unique as it possesses “shape
 14 memory.” That is, Nitinol will change shape according to change in temperature, and
 15 then, retake its prior shape after returning to its initial temperature. This quality makes
 16 Nitinol appealing for use in certain medical devices, including IVC Filters.
- 17 23. Soon after the BRF’s introduction to the market, reports were made that portions of
 18 the device were fracturing and migrating to the anatomy and vital organs of the
 19 patients in whom it was implanted. These reports continued to surface and were made
 20 to healthcare providers, the FDA, and to the Defendants. In fact, as early as 2003, the
 21 Defendants were made aware that the BRF was flawed and was causing injury and
 22 death to patients who had the filter implanted in their bodies.
- 23 24. The BRF was plagued with manufacturing and design defects which caused it to
 24 experience a significant rate of fracture and migration of the device. Studies performed
 25 in the medical and scientific communities established that the BRF had a 21% to
 26 31.7% rate of fracture.
- 27 25. The failure of the BRF, as aforesaid, was attributable, in part, to the fact that the BRF
 28 was not designed so as to be able to withstand the normal anatomical and physiological

loading cycles exerted *in vivo*.

26. Sometime after 2003, the Defendants made a decision to introduce a substitute vena cava filter for Bard Peripheral Vascular's vena cava filter product line. This substitute vena cava filter was meant to replace the BRF. It was to be called the "G2 Filter." G2 stands for "second generation."

27. In 2005, the Defendants submitted an application to the Food and Drug Administration ("FDA") for introduction of the G2TM Filter to the global market. The application was submitted under Section 510(k) of the United States Food, Drug and Cosmetic Act ("Act") of 1976 (21 U.S.C. 321 *et seq.* Under Section 510(k), a medical device manufacturer may represent that the device which is offered for approval is "substantially similar" to a "predicate device." With regard to the G2 Filter, the Defendants represented to the F.D.A that it was substantially similar to the RecoveryTM Filter System (the predicate device).

28. The Defendants first received clearance from the FDA to market the G2TM Filter System as a permanent placement vena cava filter. The Defendants began selling the G2TM Filter System in September of 2005. Later, in 2008, the G2TM Filter was cleared by the FDA as a retrievable (option) IVC filter.

WHAT HAPPENS WHEN THE BRF FAILS?

29. The failure (fracture and/or migration) of the BRF leads to a number of different, and potentially fatal, complications. These complications include, but are not limited to:

- a. Death;
- b. Hemorrhage;
- c. Cardiac/pericardial tamponade (pressure caused by a collection of blood in the area around the heart);
- d. Severe and persistent pain; and
- e. Perforation of tissue, vessels and organs.

30. The person who experiences failure (fracture and/or migration) of the BRF often

1 experiences an acute onset of chest pain and shortness of breath. This typically
2 results in the person presenting to an emergency room, hospital, and/or physician for
3 evaluation.

4 31. The BRF was placed in Plaintiff's body on or about March 2004. Plaintiff discovered
5 for the first time on or about March 2015 that the BRF had fractured, injuring him by
6 causing the embolization of two arm fragments into the proximal right pulmonary arteries,
7 and the embolization of one fractured arm fragment into the right atrium of his heart.
8 Plaintiff has incurred significant medical expenses and has endured extreme pain
9 and suffering, fear of death, loss of enjoyment of life, and other losses, some of
10 which are permanent in nature. As a result of the failure of the BRF, Plaintiff lives
11 in constant fear that the BRF will continue to migrate, pierce his heart, and
12 kill him. Plaintiff has become impaired and his ability to earn wages has been
13 diminished, and will remain so in the future. The defective BRF remains in
14 Plaintiff's body. Plaintiff is required to attend regular physicians' visits and to
15 undergo imaging studies.

16 32. As a direct and proximate result of the conduct and defective product of the Bard
17 Defendants, as alleged in this Complaint, and of the failure by Defendant CPMC to
18 disclose information about said defective product that it had a duty to disclose, Plaintiff
19 Wayne Ruden has suffered permanent and continuing injury, loss of enjoyment of
20 life, pain, suffering, and impairment. Plaintiff has suffered emotional trauma, harm
21 and injuries. Plaintiff's ability to carry on the affairs of his daily life has been
22 impacted and diminished, and will continue to diminish in the future.

23 33. As a direct and proximate result of the conduct and defective product of the
24 Defendants, as alleged in this Complaint, medical monitoring is necessary for Plaintiff
25 Wayne Ruden. Medical monitoring includes:
26 a. Regularly scheduled CT scans or other appropriate imaging studies; and/or
27 b. Potential cardiac catheterization or other endovascular procedure to detect the
28 presence of migrated pieces of the BRF; and or physicians' visits and examinations.

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2 **THE DEFENDANTS' KNOWLEDGE OF THE FAILURE OF THE BRF AND THE**
3 **DANGERS ASSOCIATED WITH THE DEVICE**

4 34. Upon information and belief, Plaintiff alleges that, at all pertinent times including prior
5 to the implantation of the BRF in Plaintiff in March 2004, the Bard Defendants C.R.
6 Bard, Inc. and Bard Peripheral Vascular, Inc. were aware and had knowledge of the
7 fact that the BRF was defective and unreasonably dangerous and was causing injury
8 and death to patients who had received the BRF.

9 35. Upon information and belief, the Bard defendants caused regulatory approval to be
10 obtained for the device through deceptive means, and with full knowledge of its
11 dangerous propensities and unacceptable failure rate.

12 36. Upon information and belief, Plaintiff alleges that CPMC was aware and had
13 knowledge of the fact that the BRF was defective and unreasonably dangerous and
14 was causing injury and death to patients who had received the BRF.

15 37. Data established that the failure rate of the BRF was/is exceedingly higher than the
16 rates the Defendants have published in the past, and currently continue to publish to the
17 medical community, members of the public, and the FDA.

18 38. Over 921 adverse events were identified by the FDA through a warning issued in
19 August of 2010 regarding risks associated with IVC filter complications.

20 39. Upon information and belief, from the time the BRF became available on the market,
21 the Bard Defendants embarked on an aggressive campaign of "off-label marketing"
22 concerning the BRF. This included representations made to physicians, healthcare
23 professionals, and other members of the medical community that the BRF was
24 safe and effective for retrievable use prior to the FDA clearing the BRF for
25 retrievable use in 2008.

26 40. The conduct of the Bard Defendants C.R. Bard, Inc. and Bard Peripheral Vascular,
27 Inc. as alleged in this Complaint, constituted willful, wanton, gross and outrageous
28 corporate conduct that demonstrates a conscious disregard for the safety of the Plaintiff

Wayne Ruden. The Bard Defendants had actual knowledge of dangers to the life health and well-being of the Plaintiff Wayne Ruden presented by the BRF, yet consciously failed to act reasonably to:

- a. Inform or warn the Plaintiff, his physicians, or the public at large of the dangers; and
- b. Recall the BRF from the market in a timely and safe fashion;

41. Despite having knowledge at all pertinent times of the unreasonably dangerous and defective nature of the product, the Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc. consciously disregarded the known risks, failed to warn physicians and existing users of the great risk of long-term retention of the device, and continued to actively market and offer for sale the BRF.

42. Plaintiff further alleges that the Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc. acted in a willful, wanton and gross manner, and in total disregard for the health and safety of the users or consumers of its BRF, including Plaintiff Wayne Ruden, and acted to serve their own interests and consciously pursued a course of conduct knowing that such conduct created a substantial risk of significant harm to other persons. Therefore, Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc. should be required to pay a punitive or exemplary damage award to the Plaintiff.

FIRST CAUSE OF ACTION: NEGLIGENCE

(BARD DEFENDANTS AND DOES 1-100 INCLUSIVE)

43. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

44. At all times relevant to this cause of action, the Bard Defendants were in the business of designing, developing, setting specifications, manufacturing, marketing, selling, and distributing the BRF.

45. The Bard Defendants designed, manufactured, marketed, inspected, labeled, promoted, distributed and sold the BRF that was implanted in Plaintiff.

1 46. The Bard Defendants had a duty to exercise reasonable and prudent care in the
2 development, testing, design, manufacture, inspection, marketing, labeling, promotion,
3 distribution and sale of the BRF so as to avoid exposing others to foreseeable and
4 unreasonable risks of harm.

5 47. At the time the BRF was implanted in Plaintiff's body, all Defendants knew or
6 reasonably should have known that the BRF was dangerous or was likely to be dangerous
7 when used in its intended or reasonably foreseeable manner.

8 48. At the time of manufacture and sale of the BRF, the Bard Defendants knew or should
9 have known that the BRF:

- 10 a. Was designed and manufactured in such a manner so as to present an unreasonable
11 risk of fracture of portions of the device;
12 b. Was designed and manufactured so as to present a unreasonable risk of migration
13 of the device and/or portions of the device; and/or
14 c. Was designed and manufactured so as to present a unreasonable risk of the device
15 tilting and/or perforating the vena cava wall; and/or
16 d. Was designed and manufactured to have unreasonable and insufficient strength or
17 structural integrity to withstand normal placement within the human body.

18 49. At the time of manufacture and sale of the BRF, the Bard Defendants knew or should
19 have known that using the BRF in its intended use or in a reasonably foreseeable manner
20 created a significant risk of a patient suffering severe health side effects, including, but
21 not limited to: hemorrhage; cardiac/pericardial tamponade; cardiac arrhythmia and other
22 symptoms similar to myocardial infarction; perforations of tissue, vessels and organs;
23 and other severe personal injuries and diseases, which are permanent in nature, including,
24 but not limited to, death, physical pain and mental anguish, scarring and disfigurement,
25 diminished enjoyment of life, continued medical care and treatment due to chronic
26 injuries/illness proximately caused by the device; and the continued risk of requiring
27 additional medical and surgical procedures including general anesthesia, with attendant
28 risk of life threatening complications.

- 1 50. At the time the BRF was implanted in Plaintiff's Body, all Defendants knew or
2 reasonably should have known that consumers of the BRF would not realize the danger
3 associated with using the device in its intended use and/or in a reasonably foreseeable
4 manner.
- 5 51. Defendants breached their duty to exercise reasonable and prudent care in the
6 development, testing, design, manufacture, inspection, marketing, labeling, promotion,
7 distribution and sale of the BRF in, among other ways, the following acts and omissions:
- 8 a. Designing and distributing a product in which they knew or should have known that
9 the likelihood and severity of potential harm from the product exceeded the burden of
10 taking safety measures to reduce or avoid harm;
 - 11 b. Designing and distributing a product in which they knew or should have known that
12 the likelihood and severity of potential harm from the product exceeded the
13 likelihood of potential harm from other device available for the same purpose;
 - 14 c. Failing to use reasonable care in manufacturing the product and producing a product
15 that differed from their design or specifications or from other typical units from the
16 same production line;
 - 17 d. Failing to use reasonable care to warn or instruct, including pre- and post-sale,
18 Plaintiff, Plaintiff's physicians, or the general health care community about the
19 BRF's substantially dangerous condition or about facts making the product likely to
20 be dangerous;
 - 21 e. Failing to perform reasonable pre and post-market testing of the BRF to determine
22 whether or not the product was safe for its intended use;
 - 23 f. Failing to provide adequate instructions, guidelines, and safety precautions, including
24 pre- and post-sale, to those persons to whom it was reasonably foreseeable would
25 prescribe, use, and implant the BRF;
 - 26 g. Advertising, marketing and recommending the use of the BRF, while concealing and
27 failing to disclose or warn of the dangers known by Defendants to be connected with
28 and inherent in the use of the BRF;

- h. Representing that the BRF was safe for its intended use when in fact, Defendants knew and should have known the product was not safe for its intended purpose;
- i. Continuing manufacture and sale of the BRF with the knowledge that said product was dangerous and not reasonably safe, and failing to comply with good manufacturing regulations of the Food and Drug Administration;
- j. Failing to use reasonable and prudent care in the design, research, manufacture, and development of the BRF so as to avoid the risk of serious harm associated with the use of the BRF;
- k. Advertising, marketing, promoting and selling the BRF for uses other than as approved and indicated in the product's label;
- l. Failing to establish an adequate quality assurance program used in the manufacturing of the BRF; and
- m. Failing to establish and maintain an adequate post-market surveillance program.

52. A reasonable manufacturer, distributor, seller or medical provider under the same or similar circumstances would not have engaged in the before-mentioned acts and omissions.

53. As a direct and proximate result of the foregoing negligent acts and omissions by Defendants, Plaintiff has suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

SECOND CAUSE OF ACTION: NEGLIGENCE

(CPMC AND DOES 1-100 INCLUSIVE)

54. Plaintiff re-alleges each and every allegation in this Complaint and incorporates each allegation into this Count, as if set forth at length, in its entirety.

55. CPMC, through its own acts and the acts of its agents, created a fiduciary or special relationship with the Plaintiff when they and their agents recommended and advised the insertion of a BRF in Plaintiff, and when they and their agents inserted a BRF in Plaintiff

on or about March 2004.

56. The implantation of the BRF in Plaintiff created a danger, which arose from the fiduciary or special relationship between CPMC and plaintiff.

57. CPMC therefore had an ongoing duty to reasonably warn the Plaintiff of newly-discovered risks related to this danger based on their fiduciary and special relationship with the Plaintiff.

58. On August 9, 2010, the FDA issued a warning letter regarding IVC filters, reporting 921 adverse events associated with the devices. The FDA advised that the events could be related to a retrievable filter remaining in the body for long periods of time.

59. The FDA advised treaters to consider the risks and benefits of filter removal for each patient.

60. On information and belief, CPMC received this warning.

61. CPMC failed to communicate with the Plaintiff, including by requesting that he undergo reasonable imaging examinations to determine the status of the BRF in his body or by asking him to undergo other appropriate and reasonable testing or examination or by providing information related to his health.

62. CPMC did not act with reasonable care when it failed to communicate with the Plaintiff in said fashion. Its failure to use reasonable care was gross, oppressive and malicious.

THIRD CAUSE OF ACTION

STRICT PRODUCTS LIABILITY - FAILURE TO WARN

(BARD DEFENDANTS AND DOES 1-100 INCLUSIVE)

63. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

64. The Bard Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed and sold the BRF, including the one implanted into Plaintiff, into the stream of commerce and in the course of same, directly advertised and marketed the device to consumers or persons responsible for consumers.

1 65. At the time the Bard Defendants designed, manufactured, prepared, compounded,
2 assembled, processed, marketed, labeled, distributed, and sold the device into the stream
3 of commerce, the Bard Defendants knew or should have known the device presented an
4 unreasonable danger to users of the product when put to its intended and reasonably
5 anticipated use.

6 66. Defendants knew or should have known at the time the BRF was implanted in Plaintiff,
7 that the BRF, *inter alia*, posed a significant and higher risk than other similar devices of
8 device failure (fracture, migration, tilting, and perforation of the vena cava wall) and
9 resulting serious injuries.

10 67. Therefore, Defendants had a duty to warn of the risk of harm associated with the use of
11 the device and to provide adequate instructions on the safe and proper use of the device.
12 Defendants further had a duty to warn of dangers and proper safety instructions that it
13 became aware of even after the device was distributed and implanted in Plaintiff.

14 68. Despite this duty, Defendants failed to adequately warn of material facts regarding the
15 safety and efficacy of the BRF, and further failed to adequately provide instructions on
16 the safe and proper use of the device.

17 69. No health care provider, including Plaintiff's physicians, or patient would have used the
18 device in the manner directed, had those facts been made known to the prescribing
19 healthcare providers and/or ultimate users of the device.

20 70. The health risks associated with the device as described herein are of such a nature that
21 ordinary consumers would not have readily recognized the potential harm.

22 71. Plaintiff and Plaintiff's health care providers used the device in a normal, customary,
23 intended, and foreseeable manner, namely as a surgically implanted device used to
24 prevent pulmonary embolisms.

25 72. After it was implanted, the device continued to function in a normal, customary,
26 intended, and foreseeable manner, namely as a surgically implanted device used to
27 prevent pulmonary embolisms.

28 73. Therefore, the BRF implanted in Plaintiff was defective and unreasonably dangerous at

1 the time of release into the stream of commerce due to inadequate warnings, labeling
2 and/or instructions accompanying the product.

3 74. The BRF implanted in Plaintiff was in the same condition as when it was manufactured,
4 inspected, marketed, labeled, promoted, distributed and sold by the Bard Defendants.

5 75. As a direct and proximate result of Defendants' lack of sufficient warning and/or
6 instructions, Plaintiff has suffered and will continue to suffer serious physical injuries,
7 economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be
8 determined at trial.

9 **FOURTH CAUSE OF ACTION**

10 **STRICT PRODUCTS LIABILITY –**

11 **DESIGN DEFECT – CONSUMER EXPECTATION**

12 **(BARD DEFENDANTS AND DOES 1-100 INCLUSIVE)**

13 76. Plaintiff re-alleges and incorporates by reference each and every allegation contained in
14 the foregoing paragraphs as though fully set forth herein.

15 77. At all times relevant to this action, the Bard Defendants developed, tested, designed,
16 manufactured, inspected, labeled, promoted, distributed and sold into the stream of
17 commerce the BRF, including the one implanted in Plaintiff.

18 78. The BRF was expected to, and did, reach its intended consumers without substantial
19 change in the condition in which it was in when it left Defendants' possession. In the
20 alternative, any changes that were made to the BRF implanted in Plaintiff were
21 reasonably foreseeable to Defendants.

22 79. The BRF implanted in Plaintiff was defective in design because it failed to perform as
23 safely as an ordinary consumer would have expected it to perform at the time of use.

24 80. The BRF implanted in Plaintiff was defective in design, in that its risks of harm exceeded
25 its claimed benefits.

26 81. Plaintiff and Plaintiff's health care providers used the BRF in a manner that was
27 reasonably foreseeable to and intended by Defendants.

28 82. Neither Plaintiff, nor Plaintiff's health care providers could have by the exercise of

1 reasonable care discovered the device's defective condition or perceived its unreasonable
2 dangers prior to Plaintiff's implantation with the device.

3 83. As a direct and proximate result of the BRF's defective design, Plaintiff has suffered and
4 will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life,
5 ongoing fear and dread, disability, and other losses, in an amount to be determined at
6 trial.

7 **FIFTH CAUSE OF ACTION**

8 **STRICT PRODUCTS LIABILITY –**

9 **DESIGN DEFECT – RISK-BENEFIT TEST**

10 **(BARD DEFENDANTS AND DOES 1-100 INCLUSIVE)**

11 84. Plaintiff re-alleges and incorporates by reference each and every allegation contained in
12 the foregoing paragraphs as though fully set forth herein.

13 85. At all times relevant to this action, the Bard Defendants developed, tested, designed,
14 manufactured, inspected, labeled, promoted, distributed and sold into the stream of
15 commerce the BRF, including the one implanted in Plaintiff.

16 86. As a direct and proximate result of the BRF's defective design, Plaintiff has suffered and
17 will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life,
18 ongoing fear and dread, disability, and other losses, in an amount to be determined at
19 trial.

20 87. The BRF implanted in Plaintiff was defective in design, in that its risks of harm exceeded
21 its claimed benefits

22 88. The BRF implanted in Plaintiff was defective in design because it was not designed to
23 withstand the stress of long-term implantation *in vivo*.

24 89. The BRF implanted in Plaintiff was defective in design because of the unacceptably high
25 risk of fracture and fragmentation.

26 90. The BRF implanted in Plaintiff was defective in design, because, on information and
27 belief, safer alternative designs existed. An example is the inferior vena cava filter
28 designs used by other manufacturers that did not result in such a high fragmentation rate.

1 91. The BRF implanted in Plaintiff was defective in design because, on information and
2 believe, the cost of an alternative design was less than the grave risk of releasing the
3 product onto the market in the state it was released.

4 **SIXTH CAUSE OF ACTION**

5 **STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT**

6 **(BARD DEFENDANTS AND DOES 1-100 INCLUSIVE)**

7 92. Plaintiff re-alleges and incorporate by reference each and every allegation contained in
8 the foregoing paragraphs as though fully set forth herein.

9 93. The Bard Defendants designed, set specifications, manufactured, prepared, compounded,
10 assembled, processed, marketed, labeled, distributed, and sold the BRF that was
11 implanted into Plaintiff.

12 94. The BRF implanted in Plaintiff contained a condition, which Defendants did not intend;
13 at the time it left Defendants' control and possession.

14 95. Plaintiff and Plaintiff's health care providers used the device in a manner that was
15 reasonably foreseeable to Defendants.

16 96. As a result of this condition, the product injured Plaintiff and failed to perform as safely
17 as an ordinary consumer would expect when used in a reasonably foreseeable manner.

18 97. As a direct and proximate result of the BRF's manufacturing defect, Plaintiff has suffered
19 and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of
20 life, disability, and other losses, in an amount to be determined at trial.

21 **SEVENTH CAUSE OF ACTION**

22 **BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY**

23 **(BARD DEFENDANTS AND DOES 1-100 INCLUSIVE)**

24 98. Plaintiff re-alleges and incorporates by reference each and every allegation contained in
25 the foregoing paragraphs as though fully set forth herein.

26 99. At all times relevant to this action, Defendants designed, researched, developed,
27 manufactured, tested, labeled, inspected, advertised, promoted, marketed, sold, and
28 distributed into the stream of commerce the BRF for use as a surgically implanted device

1 used to prevent pulmonary embolisms and for uses other than as approved and indicated
2 in the product's instructions, warnings, and labels.

3 100. At the time and place of the sale, distribution, and supply of the Defendants' BRF to
4 Plaintiff by way of Plaintiff's health care providers and medical facilities, Defendants
5 expressly represented and warranted, by labeling materials submitted with the product,
6 that the BRF was safe and effective for its intended and reasonably foreseeable use.

7 101. Defendants knew of the intended and reasonably foreseeable use of the BRF, at the time
8 they marketed, sold, and distributed the product for use by Plaintiff, and impliedly
9 warranted the product to be of merchantable quality, and safe and fit for its intended use.

10 102. Defendants impliedly represented and warranted to the healthcare community, Plaintiff
11 and Plaintiff's health care providers, that the BRF was safe and of merchantable quality
12 and fit for the ordinary purpose for which the product was intended and marketed to be
13 used.

14 103. The representations and implied warranties made by Defendants were false, misleading,
15 and inaccurate because the BRF was defective, unsafe, unreasonably dangerous, and not
16 of merchantable quality, when used in its intended and/or reasonably foreseeable manner.
17 Specifically, at the time of Plaintiff's purchase of the BRF from the Defendants, through
18 Plaintiff's physicians and medical facilities, it was not in a merchantable condition in
19 that:

20 a. It was designed in such a manner so as to be prone to a statistically high incidence of
21 failure, including fracture, migration, excessive tilting, and perforation of the inferior
22 vena cava;

23 b. It was designed in such a manner so as to result in a statistically significant incidence of
24 injury to the organs and anatomy; and

25 c. It was manufactured in such a manner so that the exterior surface of the BRF was
26 inadequately, improperly and inappropriately prepared and/or finished causing the
27 device to weaken and fail.

28 104. Plaintiff and Plaintiff's health care providers reasonably relied on the superior skill and

1 judgment of Defendants as the designers, researchers and manufacturers of the product,
 2 as to whether the BRF was of merchantable quality and safe and fit for its intended use,
 3 and also relied on the implied warranty of merchantability and fitness for the particular
 4 use and purpose for which the BRF was manufactured and sold.

5 105. Defendants placed the BRF into the stream of commerce in a defective, unsafe, and
 6 unreasonably dangerous condition, and the product was expected to and it did reach
 7 Plaintiff without substantial change in the condition in which the BRF was manufactured
 8 and sold.

9 106. Defendants breached their implied warranty because their BRF was not fit for its
 10 intended use and purpose.

11 107. As a proximate result of Defendants breaching their implied warranties, Plaintiff has
 12 suffered and will continue to suffer serious physical injuries, economic loss, loss of
 13 enjoyment of life, disability, and other losses, in an amount to be determined at trial.

14 **EIGHTH CAUSE OF ACTION**

15 **NEGLIGENT MISREPRESENTATION**

16 **(BARD DEFENDANTS AND DOES 1-100 INCLUSIVE)**

17 108. Plaintiff re-alleges and incorporates by reference each and every allegation contained in
 18 the foregoing paragraphs as though fully set forth herein.

19 109. At all times relevant to this cause, and as detailed *supra*, Defendants negligently
 20 provided Plaintiff, Plaintiff's health care providers, and the general medical community
 21 with false or incorrect information, or omitted or failed to disclose material information
 22 concerning the BRF, including, but not limited to, misrepresentations relating to the
 23 following subject areas:

- 24 a. The safety of the BRF;
- 25 b. The efficacy of the BRF;
- 26 c. The rate of failure of the BRF;
- 27 d. The approved uses of the BRF.

28 110. The information distributed by Defendants to the public, the medical community and

- 1 Plaintiff's health care providers was in the form of reports, press releases, advertising
2 campaigns, labeling materials, print advertisements, commercial media containing
3 material representations, which were false and misleading, and contained omissions and
4 concealment of the truth about the dangers of the use of the BRF. Defendants made the
5 foregoing misrepresentations knowing that they were false or without reasonable basis.
6 On information and belief, these materials included instructions for use and warning in a
7 document that was included in the package of the BRF that was implanted in Plaintiff.
- 8 111. Defendants' intent and purpose in making these misrepresentations was to deceive and
9 defraud the public and the medical community, including Plaintiff's health care
10 providers; to gain the confidence of the public and the medical community, including
11 Plaintiff's health care providers; to falsely assure them of the quality of the BRF and its
12 fitness for use; and to induce the public and the medical community, including
13 Plaintiff's healthcare providers, to request, recommend, prescribe, implant, purchase, and
14 continue to use the BRF.
- 15 112. The foregoing representations and omissions by Defendants were in fact false. The BRF
16 is not safe, fit, and effective for human use in its intended and reasonably foreseeable
17 manner. The use of the BRF is hazardous to the user's health, and said device has a
18 serious propensity to cause users to suffer serious injuries, including without limitation,
19 the injuries Plaintiff suffered. Further, the device has a significantly higher rate of failure
20 and injury than do other comparable devices.
- 21 113. In reliance upon the false and negligent misrepresentations and omissions made by
22 Defendants, Plaintiff and Plaintiff's health care providers were induced to, and did use
23 the BRF, thereby causing Plaintiff to sustain severe and permanent personal injuries.
- 24 114. Defendants knew and had reason to know that Plaintiff, Plaintiff's health care providers,
25 and the general medical community did not have the ability to determine the true facts
26 intentionally and/or negligently concealed and misrepresented by Defendants, and would
27 not have prescribed and implanted same, if the true facts were known to them.
- 28 115. Defendants had sole access to material facts concerning the defective nature of the

1 product and its propensity to cause serious and dangerous side effects in the form of
2 dangerous injuries and damages to persons who are implanted with the BRF.

3 116. At the time Defendants failed to disclose and misrepresented the foregoing facts, and at
4 the time Plaintiff used the BRF, Plaintiff and Plaintiff's health care providers were
5 unaware of said Defendants' negligent misrepresentations and omissions.

6 117. Plaintiff, Plaintiff's health care providers and the general medical community reasonably
7 relied upon misrepresentations and omissions made by Defendants where the concealed
8 and misrepresented facts were critical to understanding the true dangers inherent in the
9 use of the BRF.

10 118. Plaintiff and Plaintiff's health care provider's reliance on the foregoing
11 misrepresentations and omissions by Defendants' were the direct and proximate cause of
12 Plaintiff's injuries as described herein.

13 **NINTH CAUSE OF ACTION**

14 **BREACH OF FIDUCIARY DUTY**

15 **(CPMC AND DOES 1-100 INCLUSIVE)**

16 119. Plaintiff re-alleges each and every allegation in this Complaint and incorporates each
17 allegation into this Count, as if set forth at length, in its entirety.

18 120. CPMC, through its own acts and the acts of its agents, created a fiduciary or special
19 relationship with the Plaintiff when its and its agents recommended and advised the
20 insertion of a BRF in Plaintiff, and when it and its agents inserted a BRF in Plaintiff on or
21 about March 2004.

22 121. The implantation of the BRF in Plaintiff created a danger, which arose from the fiduciary
23 or special relationship between CPMC and plaintiff.

24 122. CPMC therefore had an ongoing duty to warn the Plaintiff of newly-discovered risks
25 related to this danger based on its fiduciary and special relationship with the Plaintiff.

26 123. On August 9, 2010, the FDA issued a warning letter regarding IVC filters, reporting 921
27 adverse events associated with the devices. The FDA advised that the events could be
28 related to a retrievable filter remaining in the body for long periods of time.

1 124. The FDA advised treaters to consider the risks and benefits of filter removal for each
2 patient.

3 125. CPMC did not advise the Plaintiff of the FDA warning or of the association of adverse
4 events with a retrievable IVC filter remaining in the body for a long period of time, even
5 though the BRF had already been in the Plaintiff's body for over 6 years when the
6 warning was issued.

7 126. CPMC did not contact the Plaintiff to obtain information or to advise testing to gather all
8 possible information on the severe dangers to which they knew the Plaintiff was exposed.

9 **TENTH CAUSE OF ACTION**

10 **NEGLIGENCE – RECALL/RETROFIT**

11 **(ALL DEFENDANTS AND DOES 1-100 INCLUSIVE)**

12 127. Plaintiff re-alleges each and every allegation in this Complaint and incorporates each
13 allegation into this Count, as if set forth at length, in its entirety.

14 128. Defendants manufactured, distributed and sold the BRF.

15 129. Defendants knew or reasonably should have known that the BRF was dangerous or was
16 likely to be dangerous when used in a reasonably foreseeable manners.

17 130. On August 9, 2010, the FDA issued a warning letter regarding IVC filters, reporting 921
18 adverse events associated with the devices. The FDA advised that the events could be
19 related to a retrievable filter remaining in the body for long periods of time.

20 131. The FDA advised treaters to consider the risks and benefits of filter removal for each
21 patient.

22 132. After learning of this defect, Defendants did not advise the Plaintiff of the FDA warning
23 or of the association of adverse events with a retrievable IVC filter remaining in the body
24 for a long period of time, even though the BRF had already been in the Plaintiff's body for
25 over 6 years when the warning was issued.

26 133. The Defendants did not contact the Plaintiff to obtain information or to advise testing to
27 understand the severe dangers to which they knew the Plaintiff was exposed.

28 134. The Defendants did not take available actions to recall the BRF from the market.

1 135. A reasonable manufacturer, distributor, seller or health care provider, under the same or
2 similar circumstances, would have recalled the BRF.

3 136. Plaintiff Wayne Ruden was harmed by this conduct.

4 137. Defendants' failure to recall the BRF was a substantial factor in causing Plaintiff Wayne
5 Ruden's harm.

6 **PUNITIVE DAMAGES ALLEGATIONS**

7 **(ALL DEFENDANTS AND DOES 1-100 INCLUSIVE)**

8 138. Plaintiff re-alleges each and every allegation in this Complaint and incorporates each
9 allegation into this Count, as if set forth at length, in its entirety.

10 139. Plaintiff is entitled to an award of punitive and exemplary damages based upon
11 Defendants' intentional, willful, knowing, fraudulent, malicious acts, omissions, and
12 conduct, and their complete and total reckless disregard for the public safety and welfare.

13 140. Defendants had knowledge of, and were in possession of evidence demonstrating that,
14 the BRF was defective and unreasonably dangerous and had a substantially higher failure
15 rate than did other similar devices on the market. Yet, Defendants failed to:

16 a. Withdraw the BRF from the market as soon as they learned of its excessive dangers;

17 b. Withdraw the BRF from the market once the FDA issued its warning letter;

18 c. Inform or warn Plaintiff or his health care providers of the excessive dangers prior to or
19 after the insertion of the BRF into his body;

20 d. Establish and maintain an adequate quality and post-market surveillance system; and

21 e. Timely inform the Plaintiff that the FDA had issued a warning for the BRF.

22 141. Defendants so acted to serve their own pecuniary interests. Having reasons to know and
23 consciously disregarding the substantial risk that their product might kill or significantly
24 harm patients, or significantly injure and impair the rights of others, Defendants
25 consciously pursued a course of conduct knowing that such conduct created a substantial
26 risk of significant harm to other persons.

27 142. Alternatively, Defendants recklessly and willfully pursued a course of conduct knowing
28 that such conduct created a substantial risk of significant harm to other persons.

1 143. As a direct, proximate, and legal result of Defendants' acts and omissions as described
2 herein, and Plaintiff implantation with Defendants' defective product, Plaintiff has
3 suffered and will continue to suffer serious physical injuries, economic loss, loss of
4 enjoyment of life, disability, and other losses, in an amount to be determined at trial.

5 **PRAYER FOR DAMAGES**

6 **WHEREFORE**, Plaintiff, Wayne Ruden, prays for relief on the entire complaint, as
7 follows:

8 a. Judgment to be entered against all defendants on all causes of action of this
9 Complaint, including but not limited to:

- 10 1. Physical pain and suffering in the past and which, in reasonable
11 probability, he will continue to suffer in the future;
- 12 2. Physical impairment and incapacity in the past and which, in reasonable
13 probability, he will continue to suffer in the future;
- 14 3. Mental anguish in the past and which, in reasonable probability, he will
15 sustain in the future;
- 16 4. Reasonable and necessary medical expenses for treatment received in the
17 past and, based upon reasonable medical probability, the reasonable
18 medical expenses he will need in the future;
- 19 5. Disfigurement in the past and which, in reasonable probability, he will
20 continue to suffer in the future;
- 21 6. Loss of earning capacity in the past and future; and
- 22 7. Punitive damages.

23 b. Plaintiff be awarded full, fair, and complete recovery for all claims and causes of
24 action relevant to this action;

25 c. Plaintiff be awarded all appropriate costs, fees, expenses, and pre-judgment and post
26 judgment interest pursuant to the laws of the State of California as authorized by law
27 on the judgments entered in Plaintiff's behalf; and,

28 d. Such other relief the court deems just and proper.

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Dated: October 7, 2015

ONGARO PC

By:  _____

Glen Turner
Attorneys for Plaintiff
WAYNE RUDEN